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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,808	06/20/2005	Hans-Ulrich Petercit	268104US0PCT	6684
22850 7590 09/20/2007 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET. ALEXANDRIA, VA 22314			EXAMINER LE, HOA T	
			ART UNIT 1773	PAPER NUMBER
			NOTIFICATION DATE 09/20/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

Application No.

10/539,808

Applicant(s)

PETEREIT ET AL.

Examiner

H. T. Le

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                    |                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                               | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>Aug. 2005</u> . | 6) <input type="checkbox"/> Other: ____                                                |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant specification fails to describe how the claimed drum coater, coating pan, fluidized bed apparatus or spray sifter is made. Besides page 19 (2<sup>nd</sup> and 4<sup>th</sup> paragraphs) of the instant specification that mentions perfunctorily these spraying equipments, no details are given as to the structure of these equipments and the method of making these equipments.
2. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as described is unclear whether the coating agent and the pigment are initially present as two separate solution/suspension/dispersion or as one solution/suspension/dispersion with two 'incompatible individual portions'. In other words, it is unclear what "portions" refers to. If these two materials were present as two separate solutions, it is unclear how one spray device can 'simultaneously' spray two separate solutions.

Claim 11 is meaningless because it refers to claim 10 as a method claim while the subject matter of claim 10 is a product.

Claim 12 is indefinite because the process of claim 1 (upon which claim 12 depends indirectly) does not describe how the sealing layer is formed.

Claim 13 suffers the same deficiency of claim 12.

Other claims are deemed indefinite in view of their dependency on claim 1.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Applicant's own admission or by Seaman et al (US 6,378,789).

At page 1, lines 10-21, applicant admits that coating pans and two-spray nozzle fluidized bed apparatuses have been commercially available at least since 1993 (Also see article by Abletshauser et al, page 150, right column).

Seaman teaches a spraying device comprising two nozzles.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the WO 00/05307 ("WO'307) in view of the Abletshauser article ("Film coating of pellets with insoluble polymers obtained in situ crosslinking in the fluidized bed").\*

WO'307 teaches a method of coating pharmaceutical products with a film-forming coating agent and a pigment additive by spraying. The coating agent comprises (meth)acrylate copolymer having cationic or anionic groups (see Applicant's own specification, page 1, lines 25-35). Because of the incompatibility between the coating agent and the pigment, clogging of spray nozzles occasionally occurs. Abletshauser teaches a simultaneous spraying technique using pan coating or fluidized bed coater for incompatible polymers that result in uniform distribution of incompatible components and fast drying (See Abletshauser, abstract and page 150, left column, first and second paragraphs). Therefore, one having ordinary skill in the art would have found it obvious to apply the simultaneous spraying coating method taught by Abletshauser in coating the products of WO'307 in order to achieve a uniform coating without the clogging problem.

7. Other references are cited as art of interest.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. T. Le whose telephone number is 571-272-1511. The examiner can normally be reached on 10:00 a.m. to 6:30 p.m., Mondays to Fridays.

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\* Both references were provided by Applicant.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Thi Le/  
H. (Holly) T. Le  
Primary Examiner  
Art Unit 1773

September 15, 2007